Integral Healthcare Solutions

AABB Blood Center and Donor Center Accreditation Consulting

Last reviewed October 2026 · https://www.integralhs.com/aabb-blood-center-donor-accreditation

What to have ready

- Your copy of the AABB Standards for Blood Banks and Transfusion Services, 35th edition, effective April 1, 2026 (AABB [https://www.aabb.org/standards-accreditation/standards/blood-banks-and-transfusion-services], with prices on AABB Purchase Standards [https://www.aabb.org/standards-accreditation/standards/purchase-standards]).
- A list of the AABB activities you perform, matched to the definitions in the Accreditation Activities list, Version 3 (AABB [https://www.aabb.org/docs/default-source/default-document-library/accreditation/aabb-accreditation-activities.pdf]).
- Written policies, processes and procedures (PPPs) that cover every standard, with records that show staff follow them. AABB's process page describes the assessment as testing both points (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).
- Written SOPs "for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components" under 21 CFR 606.100(b) (eCFR [https://www.ecfr.gov/current/title-21/part-606]).
- Donor eligibility records showing the determination is made before collection, per 21 CFR 630.10(a) (eCFR [https://www.ecfr.gov/current/title-21/part-630]).
- Your FDA establishment registration and product list, since 21 CFR 607.20(a) requires owners or operators of establishments "not exempt under section 510(g) of the act or subpart D of this part, that engage in the manufacture of blood products" to "register and submit a list of every blood product in commercial distribution" (eCFR [https://www.ecfr.gov/current/title-21/part-607]).
- Evidence of at least 6 months of operation in each activity you seek (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).
- Your annual collection or transfusion volume, which sets AABB's volume fee (AABB fees [https://www.aabb.org/docs/default-source/default-document-library/membership/institutional-fees.pdf]).
- A decision on whether AABB will be your CLIA provider for the activities it marks (AABB [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/blood-collection]).
- A named owner for the APEX self-assessment (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).